

composition. Examples of usable lubricating materials include, without limitation, fats, emulsifiers, waxes, magnesium stearate, calcium stearate, talc, starches, silicon dioxide, and mixtures thereof. Among the fats, or fatty materials, useful  
5 herein include, without limitation, water-insoluble, inert hydrocarbon fats or oils, or their derivatives and mixtures thereof. Such fats or fatty materials include, for example and without limitation, cocoa butter, hydrogenated vegetable tallow, hydrogenated vegetable oils, and derivative mixtures thereof.

10 Among the emulsifiers useful herein include, without limitation, alkyl aryl sulfonates, alkyl sulfates, sulfonated amides and amines, sulfated and sulfonated esters and ethers, alkyl sulfonates, polyethoxylated esters, mono- and diglycerides, diactyl tartaric esters of monoglyderides,  
15 polyglycerol esters, sorbitan esters and ethoxylates, lactylated esters, propylene glycol esters, sucrose esters and mixtures thereof. Among the waxes useful herein include, without limitation, amorphous waxes, anionic emulsifying waxes, bleached waxes, caranda waxes, cetyl esters, cationic emulsifying waxes,  
20 microcrystalline waxes, paraffins, refined waxes and mixtures thereof.

The use of particular fats, emulsifiers or waxes may allow the encapsulated product of the present inventive subject matter to provide controlled release of the active ingredient. The  
25 controlled release occurs due to the entrapment of the active material in the particular fat, emulsifier or wax.

Furthermore, other additives such as colors, binders, etc. may also be added to this mixture to form the final mixture. The final mixture is then formed into the encapsulated product  
30 of the present invention by using a tableting machine. The stations of the tableting machine are set to the desired caplet

size, which is from about 1 millimeter to about 7 millimeters diameter and length for the encapsulated.

5 The use of flavor along with the pharmaceuticals in the encapsulated product allows for flexibility in adding flavor to food items, confectionery products or chewing gum products, while delivering the pharmaceutical active ingredient to the patient. For example, delivery of two or more flavors to a single food item is possible by using encapsulated products containing different flavors in the food item. The delivery of  
10 two or more flavors is also possible in confectionery products and chewing gum products.

15 While the above final step of the method is preferred, other alternate final steps of preparing encapsulated products are contemplated as being within the scope of the inventive subject matter. In particular, the inventive subject matter also contemplates forming larger tablets with the tableting machine, then grinding the larger tablets into smaller pieces. A further final step is forming the sheets of the final product using roller compaction techniques, then grinding the sheets.

20 Advantages of preparing the inventive encapsulated product in this manner are that no heat and no moisture are needed in this process. Additionally and surprisingly, high concentrations of flavor (as well as other active ingredients) may be incorporated into the final encapsulated product.  
25 Furthermore, the encapsulated product of the present inventive subject matter is small enough that when the confectionery or chewing gum product is chewed, the encapsulated product can pass with the saliva and not be disformed by the teeth of the individual chewing, thus allowing the pharmaceutical or  
30 medicament to pass to the gastrointestinal tract.

The present inventive subject matter also contemplates

incorporating sweeteners into the encapsulated products. Examples of sweeteners that are available to be mixed in the encapsulated products of the present inventive subject matter include, without limitation, solid natural or synthetic sweeteners such as amino acid based sweeteners, dipeptide sweeteners, especially aspartame, glycerrhizin, saccharin and its salts, acesulfame salts, cyclamates, steviosides, talin, dihydrochalcone compounds and mixtures thereof. The sweetener is generally present in the encapsulated product from about 0.1% to about 70% by weight of the final encapsulated product. The present inventive subject matter also contemplates having a blend of the above sweeteners as the active ingredient in the encapsulated product.

The present inventive subject matter also contemplates the use of the encapsulated product in a food item, a confectionery product or a chewing gum product.

As used herein, the term "confectionery" means a product containing a bulking agent selected from a wide variety of materials such as sugar and, in the case of sugarless bulking agents, sugar alcohols such as sorbitol and mannitol. Confectionery material may include exemplary substances as lozenges, tables, toffee, nougat, chewy candy and so forth. In general, the bulking agent will comprise from about 5 to about 99% and preferably 20 to 95% by weight of the activated confectionery product.

Lozenges are forms intended to be sucked and held in the mouth. They may be in the form of various shapes, the most common being flat, circular, octagonal and biconvex forms. The lozenge bases are generally in two forms, hard boiled candy lozenges and compressed tablet lozenges.

The hard boiled candy lozenges are prepared from a mixture